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11 UNITED STATES DISTRICT COURT
12 FOR THE CENTRAL DISTRICT OF CALIFORNIA
13 WESTERN DIVISION
14

15 CITIZENS COMMISSION ON
16 HUMAN RIGHTS,

17 Plaintiff,

18 v.

19 UNITED STATES FOOD AND
20 DRUG ADMINISTRATION,

21 Defendant.

No. CV 18-05320 CBM (AFMx)

**ANSWER OF DEFENDANT TO
PLAINTIFF'S COMPLAINT**

22
23 Defendant, acting by and through its undersigned attorneys, hereby answers
24 the allegations in Plaintiff's Complaint as follows:

25 1. The allegations contained in the first sentence of paragraph 1 of the
26 Complaint constitute Plaintiff's characterization of the case to which no response is
27 required. To the extent a response is deemed required, Defendant denies the
28 allegations contained in paragraph 1 of the Complaint.

1 2. Defendant lacks knowledge sufficient to form a belief as to the truth
2 of the matters asserted in paragraph 2 of the Complaint and on that basis denies
3 them.

4 3. Defendant admits only that it is an agency in the United States
5 Department of Health and Human Services and has at least one duty station in Los
6 Angeles County. Defendant denies the remaining allegations contained in
7 paragraph 3 of the Complaint.

8 4. Defendant denies the allegations contained in the first two sentences
9 of paragraph 4 of the Complaint. The allegations contained in the third sentence of
10 paragraph 4 of the Complaint constitute allegations of jurisdiction to which no
11 response is required. To the extent a response is deemed required, Defendant
12 denies the allegations contained in the third sentence of paragraph 4 of the
13 Complaint.

14 5. Defendant admits that Plaintiff submitted a FOIA request to FDA on
15 June 21, 2016, but denies Plaintiff's characterization of that response, contained in
16 the first sentence of paragraph 5 of the Complaint, as "simple." Defendant admits
17 the allegations contained in the second sentence of paragraph 5 of the Complaint.

18 6. Defendant admits only that it sent an email to Plaintiff's counsel on
19 June 14, 2017, and that email speaks for itself. Defendant denies the remaining
20 allegations contained in paragraph 6 of the Complaint.

21 7. Defendant admits only that Plaintiff's counsel sent an email to the
22 FDA on June 14, 2017, and that email speaks for itself. Defendant denies the
23 remaining allegations contained in paragraph 7 of the Complaint.

24 8. Defendant admits only that it sent a follow-up email to Plaintiff's
25 counsel on June 14, 2017, and that email speaks for itself. Defendant denies the
26 remaining allegations contained in paragraph 8 of the Complaint.

27 9. Defendant admits only that there were email communications with
28 Plaintiff's counsel between July 11, 2017, and July 12, 2017, and that those emails

1 speak for themselves. Defendant denies the remaining allegations contained in
2 paragraph 9 of the Complaint.

3 10. Defendant admits only that it sent an email to Plaintiff's counsel on
4 July 24, 2017, and that email speaks for itself. Defendant denies the remaining
5 allegations contained in paragraph 10 of the Complaint.

6 11. Defendant admits only that it sent an email to Plaintiff's counsel on
7 August 14, 2017, and that email speaks for itself. Defendant denies the remaining
8 allegations contained in paragraph 11 of the Complaint.

9 12. Defendant admits only that there were email communications with
10 Plaintiff's counsel between September 20, 2017, and September 27, 2017, and
11 those emails speak for themselves. Defendant denies the remaining allegations
12 contained in paragraph 12 of the Complaint.

13 13. Deny.

14 14. Defendant admits only that Plaintiff's counsel sent FDA a letter dated
15 October 10, 2017, that there were email communications with Plaintiff's counsel
16 between October 17, 2017, and November 11, 2017, and that those emails speak
17 for themselves. Defendant denies the remaining allegations contained in paragraph
18 14 of the Complaint.

19 15. Defendant admits only that it received an administrative appeal from
20 Plaintiff's counsel by letter dated January 16, 2018, alleging "denial of access to
21 records, FDA No. 2016-5287." Defendant denies the remaining allegations
22 contained in paragraph 15 of the Complaint.

23 16. Deny.

24 17. The allegations of paragraph 17 of the Complaint constitute legal
25 conclusions to which no response is required. To the extent a response is deemed
26 required, Defendant denies the allegations contained in paragraph 17 of the
27 Complaint.

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1 18. The remainder of the Complaint constitutes Plaintiff's prayer for relief
2 to which no response is required. To the extent that a response is deemed required,
3 the allegations of the prayer for relief are denied. Plaintiff should take nothing at
4 all.

5 19. Any allegation contained in Plaintiff's Complaint that has not been
6 admitted or denied is hereby denied.

7 **FIRST AFFIRMATIVE DEFENSE**

8 The Complaint fails to state a claim against Defendant upon which relief can
9 be granted. Fed. R. Civ. P. 12(b)(6).

10 **SECOND AFFIRMATIVE DEFENSE**

11 The Complaint purports to impose obligations upon Defendant that exceed
12 those imposed by the Freedom of Information Act ("FOIA").

13 **THIRD AFFIRMATIVE DEFENSE**

14 Plaintiff is not entitled to compel the production of records that are exempt
15 from disclosure under FOIA or under other provisions of law, or to compel the
16 production of records that are not subject to FOIA.

17 **FOURTH AFFIRMATIVE DEFENSE**

18 Defendant is not improperly withholding any responsive documents.

19 **FIFTH AFFIRMATIVE DEFENSE**

20 At all times alleged in the Complaint, Defendant acted in good faith, with
21 justification, and pursuant to authority.

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1 WHEREFORE, Defendant prays for judgment dismissing Plaintiff's
2 Complaint, and awarding Defendant its costs and disbursements in this action, and
3 for such other and further relief as the Court may deem just and proper.

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5 Dated: December 10, 2018

Respectfully submitted,

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8 DAVID M. HARRIS
9 Assistant United States Attorney
10 Chief, Civil Division
11 JOANNE S. OSINOFF
12 Assistant United States Attorney
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14
15 /s/ Jason K. Axe
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17 Assistant United States Attorney
18 Attorneys for Defendant
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